IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1118

PETER H. FORSHAM, ET AL.,

Petitioners,

v.

PATRICIA R. HARRIS, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF RESPONDENT DR. CHRISTIAN R. KLIMT

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the District of Columbia Circuit (A. 217-37), the concurring opinion of Judge MacKinnon (A. 238-39), and the dissenting opinion of Judge Bazelon (A. 240-57) are reported at 587 F.2d 1128, 1139, and 1140 (D.C. Cir. 1978). The order of the court of appeals denying rehearing (A. 258) and Judge Bazelon's statement explaining his vote for rehearing (A. 259) are reported at 587 F.2d at 1148. The order of the district court (A.

180-81) denying the petitioners' motion for summary judgment and granting the respondents' motions to dismiss is not reported.

JURISDICTION

The court of appeals entered judgment on July 11, 1978. On July 25 a timely petition for rehearing and in the alternative suggestion for rehearing in banc was filed (A. 261-68). On October 17, 1978, the court of appeals denied the petition for rehearing (A. 258-60) and the suggestion for rehearing in banc (Ct. App. R. 9). The petition for writ of certiorari was filed on January 15, 1979, and was granted on May 14, 1979. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1) (1976).

STATUTES INVOLVED

This case turns upon the interpretation of the Freedom of Information Act, 5 U.S.C. § 552 (1976), which is reproduced in the appendix to the petitioners' brief at 25a.

QUESTIONS PRESENTED

A continuing research study conducted by private and state medical schools and hospitals and funded by federal grants has collected raw data upon which it has based certain conclusions. The federal government has never controlled the research and has never owned, controlled, or possessed the raw data that the petitioners seek pursuant to the Freedom of Information Act. Accordingly, this case presents the following questions of the interpretation of the Act:

1. Does the federal government's funding of the study transform the private and state institutions into federal agencies or transform the raw data into "agency records" under the Act?

2. Must the federal government, in response to a request for records under the Act, exercise whatever

rights of access it may have to obtain private and state documents, such as the raw data of the medical schools and hospitals, and thereafter make them available?

3. Does the reliance by the federal government upon the published findings of the study and upon an audit of some of the raw data transform all of the data into "agency records" under the Act?

STATEMENT OF THE CASE

The petitioners seek reversal of the decision of the court of appeals affirming the judgment of the district court, which had dismissed the petitioners' request for the production of the raw data generated in a study conducted by the University Group Diabetes Program and funded by federal grants. The court of appeals held that the federal funding of the study, federal access to the raw data compiled by the University Group, and reliance upon the published findings of the study do not convert the raw data into "agency records" under the Freedom of Information Act, 5 U.S.C. § 552 (1976).

In June 1959, a number of private physicians and scientists conceived of the idea of a long-term prospective clinical study to determine whether the treatment of mild adult-onset diabetes with insulin or tolbutamide prevented, delayed, or alleviated the principal complications (retinopathy, cardiovascular disease, nephropathy, and neuropathy) of this disease (A. 96; D. Ct. R. 4, ex. 2 to affidavit of G. Donald Whedon at 5, 7, and 8). As a result of the efforts of these physicians and scientists, a number of private and state medical schools and hospitals formed the University Group Diabetes Program to perform the study. The University Group eventually grew to include twelve participating clinics and a coordinating center at the University of Maryland School of Medicine. Between 1959 and 1961, the principal investigators who were to conduct the study prepared and evaluated its design, methods, and

objectives. The clinical part of the study began in 1961 (A. 145-46), and 1,027 patients entered the study between 1961 and 1965 (A. 134, 146).

In each of the participating clinics, the investigators allocated on a random basis recently diagnosed cases of mild adult-onset diabetes to one of four treatment groups. These groups consisted of: (1) standard diet plus placebo tablets; (2) standard diet plus a fixed dose of tolbutamide; (3) standard diet plus a fixed insulin dose; and (4) standard diet plus insulin in varying amounts dosed to maintain normal blood sugar levels. In 1963 a fifth group of standard diet plus a fixed dose of phenformin was added (A. 146).

When a patient entered the study, the clinics made an initial evaluation of his or her health. Thereafter, the clinics performed quarterly examinations to determine the degree of control of the diabetes and the development, if any, of the complications of the disease (A. 97-98). The clinics forwarded the records of these examination results to the coordinating center. The coordinating center collected and computerized these results and subjected them to periodic statistical analyses. The treatment groups were compared for the number of deaths observed in each group and the proportion among each group developing one or more complications. In addition, the coordinating center was responsible for maintaining uniformity in the records and in the laboratory techniques employed. For example, whenever a patient died, the coordinating center would forward the patient's records to two or more specialists for examination. This was done to ensure the consistency and quality of the findings. These consulting specialists were unaware of the treatment that the patient was receiving (A. 97-99).

Each of the schools and hospitals in the University Group applied for and received separate research grants from the National Institute of Arthritis, Metabolism, and Digestive Diseases[1] (the "NIAMDD") of the National Institutes of Health to fund its participation in the study. The NIAMDD provided these funds as part of its responsibility to support research in the field of diabetes and without any specific regulatory objective in mind. In 1966 the NIAMDD renewed the grants to continue the study, and in 1971 the grants again came up for review. The National Advisory Arthritis and Metabolic Diseases Council recommended their approval and gave the study a rating of "high program relevance", which was in effect a direction to the staff of the NIAMDD to provide financial support for the study (A. 146-47).

The Food and Drug Administration (the "FDA") was not involved in the planning, inception, design, or conduct of the study. The raw data of the study, such as patient charts and forms, are the property of the participating schools and hospitals and the individual investigators. The NIAMDD does not own these data. Furthermore, it is not the normal practice of either the NIAMDD or the National Institutes of Health to require grantees to submit their data for review, and submission of raw data is extremely rare. In this case, the University group has not submitted any of the data to the NIAMDD (A. 146-48).

[1] The NIAMDD is one of a number of a research institutes that collectively form the National Institutes of Health, all of which are part of the Public Health Service. The Public Health Service is the operating agency within the Department of Health, Education, and Welfare principally engaged in providing health services, conducting and supporting health research, and providing state and local aid. The Food and Drug Administration is a separate agency within the department primarily responsible for regulating the manufacture, labeling, and distribution of drugs. *See generally* Reorg. Plan No. 3 of 1966, *reprinted in* 5 U.S.C. app., at 391-95 (1976) *and in* 80 Stat. 1610 (1966).

The participating clinics are responsible for managing the day-today operations of the study. Representatives of the NIAMDD reviewed the design, methods, and objectives of the study before it began the clinical phase, but it had no involvement in the clinical phase except to review the periodic reports submitted to it. Finally, no officer or employee of the NIAMDD or of the National Institutes of Health has ever seen or possessed any of the raw data. It is estimated that the raw data consists of millions of separate documents, possibly as many as 55,000,000 documents, and many contain information that identifies patients (A. 146-48).

At the annual meeting of the American Diabetes Association on June 14, 1970, the University Group presented some of the results of its continuing study. These results indicated that, among other things, the use of tolbutamide to control mild adult-onset diabetes was no more effective than diet alone in prolonging life and that it led to a greater death rate from cardiovascular disease than was found in the groups treated with diet alone, a fixed dosage of insulin, or a variable dosage of insulin. Later that year, the University Group published these results in the Journal of the American Diabetes Association. The University Group Diabetes Program, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes, I & II*, 19 Diabetes 747 (Supp. 2, 1970) (A. 72). Both the American Diabetes Association and the American Medical Association's Council on Drugs supported the validity of the study (A. 72). Subsequently, the University Group published its findings that phenformin also generated a higher incidence of cardiovascular disease. Knatterud, Meinert, Klimt, Osborne, and Martin, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes, IV, A Preliminary Report on Phenformin Results*, 217 J.A.M.A. 777 (1971); The

University Group Diabetes Program, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes, V, Evaluation of Phenformin Therapy*, 24 Diabetes 65 (Supp. 1, 1975). From time to time, additional findings have been published. *See, e.g.*, Knatterud, Klimt, Levin, Jacobson, and Goldner, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes, VII, Mortality and Selected Nonfatal Events with Insulin Treatment*, 240 J.A.M.A. 37 (1978).

The University Group study has been criticized (A. 12-13). Accordingly, to assess the scientific quality of the study, the Director of the National Institutes of Health, in 1972, invited the President of the Biometric Society, a private organization of scientists, to appoint a committee to consider the statistical aspects of the study (A. 144). This committee evaluated the methods used in the clinical study, reviewed the published criticisms of the study, interviewed both critics and supporters of the study, and made new analyses from some of the original data. 40 Fed. Reg. 28,587, 28,590 (1975). None of the data that the University Group made available to the committee was ever submitted to the NIAMDD or any other agency of the federal government, nor were they required to be submitted (A. 148). The committee commented on the major criticisms of the study and concluded that the study's evidence of harmfulness was moderately strong. 40 Fed. Reg. at 28,590. *See also* Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents, *Report*, 231 J.A.M.A. 583, 599 (1975).

Before the report of the committee of the Biomatric Society was published, counsel for the petitioners requested from the NIAMDD, the FDA, and the Department of Health, Education, and Welfare a copy of a draft of this report and also "access to the raw data

which was accorded to the biometric study" (A. 40, 42-43, 49). On January 27, 1975, G. Donald Whedon, Director of the NIAMDD, supplied to counsel for the petitioners the galley proof of the final version of the committee's report. In addition, Dr. Whedon explained that no one in the Department of Health, Education, and Welfare had ever possessed any of the raw data of the study (A. 54). On May 6, 1975, counsel for the petitioners renewed his request for access to the raw data (A. 55). Counsel also requested the research design and protocol for the study submitted to the NIAMDD and a statement detailing all budget appropriations, allocations, and expenditures for the study (A. 56). He subsequently made a detailed request for records in the NIAMDD's files relating to the grants to the University Group (A. 63-65).

In a series of subsequent correspondence, Theodore Cooper, Acting Assistant Secretary for Health, responded that the Department of Health, Education, and Welfare had never possessed any of the raw data on which the study was based (A. 57); that all of the grantees' working documents remained in their possession and were not considered in any way to be part of the grant files maintained at the National Institutes of Health; that the National Institutes of Health had no duty to request that a grantee submit data not required as part of the grant; that, because the raw data did not belong to the Department of Health, Education, and Welfare, the Freedom of Information Act did not apply to the material requested (D. Ct. R. 4, app. to ex. 1); that neither the grants to the University Group nor the contract with the Biometric Society required the submission of the raw data to the National Institutes of Health; that the raw data was at that time in the form of microfilm and was being stored in a Maryland bank vault; and that Dr. Cooper was informed that Dr. Klimt, the director of the coordinating center, believed that the

data are protected from disclosure under Maryland law (A. 68-69). Nevertheless, all records in the NIAMDD's files on the University Group's grants and study were released to counsel for the petitioners, with two deletions that they have not challenged (A. 66-67).

On September 30, 1975, the petitioners filed suit against the respondents, the Secretary of the Department of Health, Education, and Welfare, the Assistant Secretary for Health, the Commissioner of Food and Drugs, the Director of the NIAMDD, and Dr. Christian R. Klimt, Director of the Division of Clinical Investigation at the University of Maryland School of Medicine and director[2] of the coordinating center for the University Group (A. 1, 3-11). The petitioners sought an order directing the respondents to produce the raw data of the University Group study which respondents may have possessed or to which any of the respondents may have had a right of access. The petitioners also requested that the court issue a declaratory judgment that they were entitled to these records and permanently enjoin the respondents from refusing to produce them (A. 10). On October 31, Dr. Klimt filed a motion to dismiss and a motion to quash service of process, and on November 21, the federal respondents filed a motion to dismiss and in the alternative a motion for summary judgment. The petitioners responded on December 5 with a motion for summary judgment.

On February 5, 1976, the district court entered an order denying the petitioners' motion for summary judgment and granting the respondents' motions to dismiss. Considering the various motions and the entire

[2] In July 1978, Dr. Genell L. Knatterud, Deputy Director of the Division of Clinical Investigation, became the principal investigator for the coordinating center. Dr. Klimt, however, is a co-investigator, and he remains the Director of the Division of Clinical Investigation, Department of Epidemiology and Preventive Medicine of the University of Maryland School of Medicine.

record in the case, the court found that no official or employee of the Department of Health, Education, and Welfare, the National Institutes of Health, the NIAMDD, or the FDA was then or had ever been in possession of the raw data of the University Group study, that the raw data were the property of the individual investigators and the coordinating center and remained in the possession, custody, and control of the coordinating center, that neither the individual investigators nor the coordinating center was an agency within the purview of the Freedom of Information Act, and that, consequently, the raw data were not agency records subject to disclosure under the Act (A. 180-81).

The petitioners appealed this order to the court of appeals on February 27, 1976. On July 11, 1978, the court issued its opinion and judgment affirming the district court's order. Relying on *United States v. Orleans*, 425 U.S. 807 (1976), the court held that persons or institutions that receive grants from the federal government do not on that account become government agencies. Further, citing *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975), the court concluded that the Freedom of Information Act did not impose upon federal agencies the obligation to exercise whatever rights of access they may have to the raw data to obtain the raw data to which they have access and to supply them to the general public. The court held that the general public may only demand a record that a federal agency has created or has obtained in the course of doing its work. 587 F.2d at 1136. The court also concluded that the policy considerations presented by the petitioners did not authorize it to extend the Freedom of Information Act beyond the federal agencies and agency records to which it applies. Moreover, the court discussed the policy considerations for not applying the Act to the records of federal grantees, e.g.,

the importance of preserving the autonomy of private and state entities conducting research.

Judge MacKinnon authored a short concurring opinion. In this opinion, he stated: "The plain implication derived from the language of the statute is that it does apply to records which belong to the agency or are in its possession—that is, records which the agency has created or obtained." 587 F.2d at 1139. Judge MacKinnon rejected the approach of the dissent because under it the interpretation of the statute would turn upon what a federal judge considered a significant degree of federal involvement. 587 F.2d at 1140.

Judge Bazelon, dissenting, would have applied the Act to the University Group's raw data. In his view, the federal funding for the University Group, the government's right of access to the data, and the government's reliance upon the University Group's study established a significant degree of federal involvement with the raw data, and that therefore this federal involvement converted the data into agency records. 587 F.2d at 1140.[3]

[3] The petitioners have presented to this Court numerous allegations of fact unsupported by any evidence in the record. The petitioners have done this in three ways. They have made bare assertions without citing any sources for these assertions. *See, e.g.*, petitioners' brief at 4 (the amount of grants to the University Group); 12 (concerning petitioners' knowledge about an earlier draft of the report of the Biometric Society); 32 n.39 (concerning liaison officers to the University Group); 32-33 (concerning a policy advisory board); and 39 (details of the conduct of the FDA audit). The petitioners also cite documents and sources not in the record and not provided by the petitioners. *See, e.g.*, petitioners' brief at 16 & n.17 (letter dated January 5, 1977 from Neil L. Chayet to J. Richard Crout, M.D.); 22 & n.30 (telegram from American Medical Association Executive Vice President James H. Sammons, M.D., February 2, 1979); 41 n.48 (letter from Dr. Christian R. Klimt to Dr. Crout, March 1, 1976); 53-54 (two memoranda of telephone coversations concerning the FDA audit and a letter from Dr. Crout to Dr. Klimt). Further, the petitioners have included in an appendix to their brief

SUMMARY OF ARGUMENT

The Freedom of Information Act, 5 U.S.C. § 552 (1976), first enacted by Public Law No. 89-554, 80 Stat. 383 (1966), provides that all federal executive agencies are to make available to any person agency records unless those records fall within one of nine exceptions. § 552(a)(3). The Act also provides a judicial remedy for any person who believes that the agency is improperly withholding "agency records". § 552(a)(4)(B). "Agency records" are those records made or received by any federal agency, that is, any documents and other similar material within the possession or day-to-day control of a federal agency.

The raw data that the petitioners seek are not the records of any federal agency. They are the property of the participating private and state medical schools and

documents which are not in the record and have cited these documents at 16, 17 & n.18 and at 36 n.42).

Many of these putative facts concern events that preceded the petitioners' complaint or the district court's hearing on the parties' motions, and the petitioners could have introduced into the district court proceedings evidence supporting these allegations. The respondents then would have had an opportunity to review and question any of these allegations or to place them in their proper context. The respondent believes that the petitioners' attempt to bring these allegations before this Court now is improper. However, the respondent also believes that all of these allegations, as well as the allegations of facts not found in the record but recited in secondary sources cited by the petitioners, are essentially irrelevant, and they do not contradict the undisputed facts upon which the district court's order was based. Accordingly, the respondent will not attempt to refute these allegations.

The respondent does not mean to suggest by his silence on these matters that he accepts the accuracy of the allegations or the implications that can be derived from them. In fact, he rejects these allegations and the implications that the petitioners attempt to draw, and he urges that this Court do the same. Nevertheless, even if all of these allegations were true, the respondent believes that they would not change the outcome in this case.

hospitals that comprise the University Group. The University Group, and not any agency of the federal government, possesses the raw data and has day-to-day control over them. Because neither the University Group nor its participating institutions are federal executive agencies, the data are not agency records. Furthermore, federal funding of the University Group's study, federal access to the University Group's records, and federal reliance upon both the University Group's published findings and a limited audit of some of the data do not make the University Group or its participating schools and hospitals federal agencies, and they do not change the raw data into the records of any federal agency.

The application of the Act to "agency records" and the definitions of "agency" demonstrate that Congress did not intend the Act to apply to a private or state recipient of federal funds or to its records. Indeed, the legislative history of the 1974 amendments states that the definition of agency does not include entities that receive federal appropriations but that are not controlled by the federal government. The language of the Act and its legislative history is consistent with federal court decisions holding that the federal government does not control a private or state institution because it provides it with federal funds and that such institutions are not federal agencies. Consequently, federal funding does not make the records of such entities "agency records".

Congress' choice of words requiring an agency to "make available" the records in its possession or subject to its control and the crafting of a judicial remedy for the improper "withholding" of such records expresses its intent that agencies need not use whatever rights of access that they may have to the documents of private and state entities in order to comply with a request under the Act. This intent has been recognized

by the Attorney General's contemporaneous construction of the Act and by many courts, including this Court. Such right of access or even the exercise of the right does not amount to possession of records still in the hands of private or state entities or control over those entities or their records. Thus, this access does not transform the raw data into agency records.

Finally, that a federal agency may have relied upon both the published findings of the University Group's study and an audit of some of the raw data does not make the raw data "agency records". The University Group and its participating institutions have retained day-to-day control of their raw data. In relying upon published findings, the federal government did not obtain possession of the raw data, and in conducting a limited audit of some of the raw data, the federal government did not exercise control over the raw data or take such control away from the University Group.

Congress deliberately chose to apply the Act only to records in the possession or direct control of federal agencies. Those individuals and organizations that must deal with the federal government know that their records are not subject to the Act unless the federal government obtains possession of their records or exercises such control over them or their records as to make them, in effect, federal agencies. Petitioners' argument, however, would obliterate these expectations. If the petitioners were to prevail, then every individual and every private and state entity that receives federal funds or that is subject to federal audit, or every non-federal individual or body whose work product may be relied upon by the federal government would in effect become federal agencies, and their records would be

subject to access by any person. It is clear that Congress intended no such result.[4]

ARGUMENT

THE FREEDOM OF INFORMATION ACT APPLIES ONLY TO RECORDS IN THE POSSESSION OR DIRECT CONTROL OF FEDERAL EXECUTIVE AGENCIES.

The petitioners present to this Court a strained interpretation of the Freedom of Information Act. They argue that the federal "involvement" with the University Group makes the data of the University Group's private and state medical schools and hospitals "agency records" under the Act. This "involvement" consists of the funding by the NIAMDD of the University Group's research study, the NIAMDD's alleged right of access to all of the University Group's data, and the unquantified reliance by the FDA on the published findings of the study, the Biometric Society committee report, and the FDA's limited audit of the raw data. The respondent suggests, however, that the specific language of the Act, in the context of commonly understood conventions of language and principles of law, expresses the specific as well as the general intent

[4] The issues in this case are distinct from those in Kissinger v. Reporters Committee for Freedom of the Press, No. 78-1088, and Reporters Committee for Freedom of the Press v. Kissinger, No. 78-1217 (U.S., cert. granted Apr. 16, 1979). Those cases involve the issues of whether transcripts of telephone conversations of former Secretary of State Henry A. Kissinger are personal notes not subject to the Freedom of Information Act or are agency records under the Act, and whether the district court has jurisdiction to compel an agency to obtain records not in its possession because it had physical possession of them at one time. In this case, the NIAMDD and the FDA never had physical possession of the raw data that the petitioners seek. Moreover, the raw data were created by nongovernmental scientists and physicians working at state and private institutions, unlike the transcripts in the *Kissinger* cases, which were created by a government official on government time with the use of government facilities.

that, notwithstanding any putative federal "involvement" with the University Group, the Act does not apply to the raw data that the petitioners seek.

The Act requires "each agency, upon any request for records," to "make the records" available. 5 U.S.C. § 552(a)(3) (1976). If the agency does not comply with the request, a court may enjoin the agency from withholding "agency records" and may order the production of "agency records improperly withheld". 5 U.S.C. § 552(a)(4)(B) (1976). Thus, the Act applies only to "agency records".

Although the Act does not contain a definition of "agency records", standard usage and commonly understood principles of the English language provide the meaning. "Agency records" means records of an agency. The records of an agency are the records that an agency creates, possesses, or directly controls.

This definition directly follows the earlier congressional definition of records in the Records Disposal Act of 1943, 57 Stat. 380 (1943). When Congress adopted the Freedom of Information Act, the Records Disposal Act contained the following definition of "records":

> [T]he word "records" includes all books, papers, maps, photographs, or other documentary materials regardless of physical form or characteristics, *made or received* by an agency of the United States Government in pursuance of federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions,

> procedures, operations or other activities of the Government or because of the informational value of data contained therein.

44 U.S.C. § 366 (1964) (emphasis added). This definition[5] has been recodified with only insignificant changes in 44 U.S.C. § 3301 (1976).

In interpreting the Freedom of Information Act shortly after its passage, the Attorney General cited this definition of records and concluded that the Act refers "only to records in being and in the possession or control of an agency." *Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* 23-24 (1967) [cited in this brief as *Attorney General's Memorandum*], *reprinted in* Subcomm. on Administrative Practice and Procedure, Senate Comm. on the Judiciary, *Freedom of Information Act Source Book*, S. Doc. No. 93-82, 93d Cong., 2d Sess. 194, 222 (1974) [cited in this brief as *Source Book*]. Although Congress has amended the Act three times, it has yet to question the Attorney General's reference to the definition of records in the Records Disposal Act of

[5] Although this definition contains two elements, that is, whether the documents are (1) made or received by an agency and (2) preserved or appropriate for preservation by that agency, the important element for purposes of the Freedom of Information Act is the first. Government documents made or received by an agency that are not appropriate for preservation are "nonrecord materials". 41 C.F.R. § 101-11.401-3(d)(1978). *See also* brief for federal parties in Kissinger v. Reporters Committee for Freedom of the Press, No. 78-1088, and Reporters Committee for Freedom of the Press v. Kissinger, No. 78-1217, (U.S., cert. granted Apr. 16, 1979), at 39-42. In this case, the Court need not reach the question of whether "nonrecord materials" are "agency records" within the meaning of the Freedom of Information Act, because the raw data that the petitioners seek are not documents "made or received" by a federal agency.

1943 or to change his interpretation of the meaning of "agency records".[6]

Similarly, this Court has recognized the plain import of "agency records". In summarizing the salient features of the Act in *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 221 (1978), the Court stated that the Act "requires that records and material *in the possession of federal agencies* be made available on demand to any member of the general public" (emphasis added). *See also Nichols v. United States*, 460 F.2d 671, 673 (10th Cir.), *cert. denied*, 409 U.S. 966 (1972) (stating that the Act applies to "*all* records and information in agency possession"), *aff'g Nichols v. United States*, 325 F. Supp. 130, 137 (D. Kan. 1971) (holding that "the Court may not require production of records not in custody or control of an agency").

The University Group's raw data are not the records of the federal government or any federal agency. The raw data that the petitioners seek are not contained in the records of the NIAMDD, the FDA, or any other agency in the Department of Health, Education, and Welfare and were not created by any agency, officer, or employee of the department. They have never been in possession of any officer or employee of the department (A. 54, 57, 68, 69, 143, 147, 148). The raw data are the property of the individual investigators and the

[6] *See also* Pub. L. No. 94-29, § 19, 89 Stat. 158 (1975), which amended the Securities Exchange Act of 1934, § 24, 15 U.S.C. § 78x (1976) (emphasis added), as follows:

> (a) For purposes of section 552 of Title V, the term "records" includes all applications, statements, reports, contracts, correspondence, notices, and other documents *filed with* or otherwise *obtained by* the Commission pursuant to this chapter or otherwise.

The purpose of this amendment was to make all documents filed with the Commission agency records for purposes of the Act and to provide that the Act governed all requests for these documents. S. Rep. No. 94-75, 94th Cong., 1st Sess. 136-37 (1975), *reprinted in* [1975] U.S. Code Cong. & Ad. News 179, 313-14.

University Group and are not owned by any agency of the federal government (A. 147). The University Group has not submitted any raw data to the federal government (A. 148). The FDA performed a limited audit of some of the University Group data, *see* 43 Fed. Reg. 52,732 (1978), and any documents or records that the FDA collected or created in this audit have been turned over to the petitioners (A. 202). In addition, all other documents and records in the possession of the federal government (with two deletions not challenged by the petitioners) have been turned over to the petitioners (A. 143, 202).

Faced with these facts, the petitioners have constructed an argument that the raw data are agency records because various federal agencies have had some involvement with the University Group's study. However, this involvement—funding of the study and access to certain records of the University Group by the NIAMDD and reliance by the FDA upon published findings and a limited audit—cannot transform the raw data into agency records unless the federal government has possessed the raw data or has caused the University Group's participating medical schools and hospitals to become federal agencies. As the respondent demonstrates, the factors that the petitioners cite, either separately or in combination, do not produce such a transformation. *See Ciba-Geigy v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977), (rejecting identical arguments raised by Ciba-Geigy, a manufacturer of phenformin.)

I.

THE RECEIPT OF FEDERAL FUNDS DOES NOT MAKE THE UNIVERSITY GROUP AN AGENCY OR ITS RAW DATA AGENCY RECORDS.

When the Freedom of Information Act was first passed by Public Law No. 89-554, 80 Stat. 383 (1966), and codified as part of the United States Code by Public

Law No. 90-23, 81 Stat. 54 (1967), it did not contain a definition of "agency". Because the Act is an amendment to the original section 3 of the Administrative Procedure Act, the definition of "agency" in the Administrative Procedure Act applies to it. That definition states:

> "[A]gency" means each authority of the Government or the United States, whether or not it is within or subject to review by another agency . . . .

5 U.S.C. § 551(1) (1976).

The federal courts have interpreted this definition of agency to mean any administrative unit of the federal government "with substantial independent authority in the exercise of specific functions". *Soucie v. David*, 448 F.2d 1067, 1073 (D.C. Cir. 1971) (holding that the Office of Science and Technology was an agency of the federal government and hence was subject to the Freedom of Information Act). It has also been interpreted to mean any federal entity with authority in law to make decisions. *Washington Research Project, Inc. v. Department of Health, Education and Welfare*, 504 F.2d 238, 248 (D.C. Cir. 1974) (holding that initial review groups consisting of non-governmental consultants are not agencies within the meaning of the Administrative Procedure Act and hence are not subject to the Act). *See generally* Freedman, *Administrative Procedure and the Control of Foreign Direct Investment*, 119 U. Pa. L. Rev. 1, 4-13 (1970).

Because certain federal entities, such as the United States Postal Service, attempted to avoid complying with the Act by claiming that they were not agencies within the meaning of the Administrative Procedure Act, Congress amended the Freedom of Information Act in 1974 to include a broader definition of "agency". Section 552(e) now states:

> For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

As House Report No. 93-876 explained, "the definition of 'agency' has been expanded to include those entities which may not be considered agencies under § 551(1) of title 5, U.S. Code, but which perform governmental functions and control information of interest to the public." H.R. Rep. No. 93-876, 93d Cong., 1st Sess. 8, *reprinted in* [1974] U.S. Code Cong. and Ad. News 6267, 6274. Thus, in addition to entities in the executive branch of government which have authority to make decisions, the definition of "agency" also includes corporations which are subject to substantial federal control over their day-to-day operations. *Rocap v. Indiek*, 539 F.2d 174, 177, 180 (D.C. Cir. 1976) (holding that the Federal Home Loan Mortgage Corporation was an agency within the meaning of section 552(e)).

The University Group does not fall within any of these definitions of agency. It is not an establishment in the executive branch or an independent regulatory agency. It was not created by federal law or by any of the federal agencies. It has no authority to make decisions. It exercises no power of the federal government. It is not a government corporation or a government controlled corporation. It is subject to no more control by the federal government than many other private or state institutions.

The University Group consists of twelve private and state medical schools and hospitals and a coordinating center at the University of Maryland. The physicians and scientists at the various participating institutions,

and not any agency of the federal government, originated the continuing clinical study conducted by the University Group. The only involvement of any agency of the federal government in the study was the NIAMDD's reviewing the design, methods, and objectives of the study, granting research funds to the University Group, and reviewing periodic reports submitted by the University Group (A. 146). The FDA was not involved in its planning, inception, or design (A. 146). The University Group, and no agency of the federal government, had full responsibility for the management of its day-to-day operations (A. 147).

The sole function of the University Group has been to conduct a clinical research study. It has analyzed the data from the clinical study and from time to time has published its conclusions about that data. At no time has it purported to make any governmental decisions or to exercise any governmental authority. Nor has it ever considered itself an agency of the federal government. For these reasons, the University Group is not an agency of the federal government within the meaning of the Act. *See Lombardo v. Handler*, 397 F. Supp. 792, 802 (D.D.C. 1975), *aff'd mem.*, 546 F.2d 1043 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 932 (1977) (holding that the National Academy of Sciences and its committee on motor vehicle emissions, private entities which contracted with the government to conduct studies, are not agencies within the meaning of the Act); *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523, 526-28 (S.D.N.Y. 1977) (holding that the University Group is not an agency within the meaning of the Act). *See also Kerr v. United States District Court for the Northern District of California*, 511 F.2d 192, 197 (9th Cir. 1975), *aff'd*, 426 U.S. 394 (1976) (holding that the California Adult Authority is not an agency subject to the Act).

That the University Group was funded completely by federal grants does no alter this conclusion. As

Conference Report No. 93-1200 on the 1974 amendments indicates, Congress did "not intend to include [in the definition of agency] corporations which receive appropriated funds but are neither chartered by the Federal Government nor controlled by it, such as the Corporation for Public Broadcasting." Conf. R. No. 93-1200, 93d Cong., 2d Sess. 14-15, *reprinted in* [1974] U.S. Code Cong. & Ad. News 6285, 6293. *See also Lombardo v. Handler*, 397 F. Supp. 792, 802 (D.D.C. 1975), *aff'd mem.*, 546 F.2d 1043 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 932 (1977).

The language that Congress did use in defining an agency and the conclusion that a federal agency does not include a private or state recipient of federal funds that is not controlled by the federal government are consistent with a number of decisions of this Court and other federal courts. For example, this Court held in *United States v. Orleans*, 425 U.S. 807 (1976), that a community action agency funded under the Economic Opportunity Act of 1964 was not a federal instrumentality or agency for purposes of the Federal Tort Claims Act. In reaching its conclusion, the Court stated that the determinative question was not whether the community action agency received federal money and must comply with federal standards and regulations, but whether its day-to-day operations were supervised by the federal government. The Court noted that the federal government spent billions of dollars on projects performed by people and institutions under contracts with the federal government and that federal funding affected innumerable activities of local and state government and of private institutions. The Court stated, "It is inconceivable that Congress intended to have waiver of sovereign immunity follow congressional largesse and cover countless unidentifiable classes of 'beneficiaries'." 425 U.S. at 816. Finally, the Court observed that the federal government did not control the "detailed physical performance" of all the

programs and projects that it finances by gifts, grants, contracts, or loans. 425 U.S. at 816. *See also Maryland v. United States*, 381 U.S. 41 (1965) (holding that civilian caretakers of aircraft owned by the United States and assigned to the Maryland Air National Guard were state, not federal employees, even though the caretakers were paid from federal funds and were required to comply with federal standards); *Greenya v. George Washington University*, 512 F.2d 556, 559-62 (D.C. Cir. 1975) (holding that federal funding of a university without any federal involvement in the actual management of the funded program, and the existence of a contract between the university and the federal government to teach government employees at government facilities did not make the university a governmental agency subject to the first and fifth amendments to the United States Constitution); *Spark v. Catholic University of America*, 510 F.2d 1977 (D.C. Cir. 1975) (holding that the receipt of federal funds did not convert a private university into an agency of the federal government for purposes of federal question jurisdiction); *Wahba v. New York University*, 492 F.2d 96 (2d Cir. 1974) (holding that the receipt of federal funds by a university and by the chairman of the Biochemistry Department who was conducting a research project funded by the National Institutes of Health did not transform the university or the chairman into governmental actors for purposes of the first and fourteenth amendments to the United States Constitution).

There is nothing in the Act's legislative history to suggest that Congress intended the Act to apply to the recipients of federal grants. The Act did broaden the public's rights to obtain records of federal agencies so that the public may be informed about what its government is doing. *See generally* S. Rep. No. 813, 89th Cong., 1st Sess. 2-3, 5, 10 (1965), *reprinted in Source Book* 36, 37-38, 40, 45; H.R. Rep. No. 1497, 89th

Cong., 2d Sess. 1, 12 (1966), *reprinted in* [1966] U.S. Code Cong. & Ad. News 2418, 2429; 112 Cong. Rec. 13,641 (1966) (remarks of Rep. Moss). Nevertheless, all of the examples of the unwillingness of federal officials to make available even the most innocuous records (such as a telephone book) that led to the Act's passage involved records that were in the possession of a federal agency, not in the possession of a recipient of a federal grant. *See* H.R. Rep. No. 1497 at 4-5, [1966] U.S. Code Cong. & Ad. News at 2422-23; *Freedom of Information, Hearings on S. 1666 and S. 1663 (in part) before the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary*, 88th Cong., 1st Sess. *passim* (1963) [cited in this brief as *1963 Senate Hearings*]; *Federal Public Records Law, Hearings Before a Subcomm. of the House Comm. on Government Operations*, 89th Cong., 1st Sess. *passim* (1965) [cited in this brief as *1965 House Hearings*]. Even after the Act took effect, Congress' focus remained upon providing access to government records and the reluctance of federal agencies to give up documents in their possession. *See Executive Privilege, Secrecy in Government, Freedom of Information, Hearings Before the Subcomm. on Intergovernmental Relations of the Senate Comm. on Governmental Operations and the Subcomms. on Separation of Powers and Administrative Practice and Procedure of the Senate Comm. on the Judiciary*, 93d Cong., 1st Sess. *passim* (1973) [cited in this brief as *1973 Senate Hearings*].

It is reasonable to expect that, had Congress intended the Act to apply to private and state recipients of federal grants, it would have directed some attention to the significant implications of such an application, that is, the effect upon private and state institutions receiving federal grants and upon the federal government's program of supporting research through grants. In the context of research grants, such an application would conflict with one of the major principles of

academic freedom—that a scientist be free to investigate an area, to locate data, to interpret that data, and to decide whether and when to publish the results of his investigations without the fear of interference or harassment by outside agents. *See generally* Machlup, *On Some Misconceptions Concerning Academic Freedom,* 41 A.A.U.P. Bull. 753 (1955), *reprinted in* American Association of University Professors, *Academic Freedom and Tenure,* 177, 178 (L. Joughlin ed. 1967). *See also* Morris, *Academic Freedom and Loyalty Oaths,* 28 L. & Contemp. Prob. 487, 489-90 (1963). However, if the Act applied to a research grant recipient, any member of the public could require a private or state researcher to open up his files before he has finished gathering or analyzing his data or publishing his findings. Thus, his research efforts could be subjected to harassment, misappropriations, or premature disclosures by outside interests motivated by financial, emotional, or philosophical considerations.

This prospect also raises serious questions about the federal effort to support research. Prominent physicians and scientists may not be willing to accept federal grants for research if others with a particular financial or ideological stake in the subject matter of the research could have ready access to the research documents under the Act. Thus, a decision to apply the Act to recipients of research grants requires a careful weighing of the benefits and detriments to the conduct of scientific research in the United States and the role of the federal government in this research, as well as a thorough airing of the many conflicting interests attending these issues.

On a larger scale, the extension of the Act to recipients of federal grants raises issues of federalism, for the states receive a large number of grants totallpng billions of dollars. Many states have their own acts requiring varying degrees of disclosure of state records.

Maryland, for example, has determined that a custodian of records, such as Dr. Klimt, may deny access to the specific details of research projects conducted by a state institution and shall deny access to hospital records relating to medical care and other medical information. Md. Ann. Code art. 76A, §§ 3(b)(iii) & 3(c)(vii) (1978). To the extent that the Maryland statute and other state statutes conflict with the Federal Freedom of Information Act, the application of the Federal Act to Maryland and other state agencies receiving federal grants would either make those agencies ineligible for grants or would abrogate the Maryland and other state statutes.

The proper forum for resolving these policy issues is, of course, Congress and not a court. If Congress had intended the Act to apply to federal grantees, then it would have addressed the policy questions. Certainly, Congress was aware of the tremendous amount of money it has appropriated for grant programs. In 1966, the year the Act was adopted, Congress appropriated approximately $808 million to the National Institutes of Health for medical research, which included almost $675 million in the form of grants and contracts for research at nonfederal institutions. U.S. Dep't of Health, Education, and Welfare, *Resources for Medical Research,* Report No. 10 at 9 (1967). For the fiscal year July 1, 1966–June 30, 1967, the federal government budgeted approximately one and one-half billion dollars for basic research at universities and colleges through grants and contracts. Bureau of the Budget, *Special Analyses of the United States Budget, 1967,* at 116-17. For that fiscal year, grants to state and local government totaled 14.5 billion dollars. *Id.* at 137.

Furthermore, during the hearings in 1972 on the operation of the Act, John F. Sherman, Deputy Director of the National Institutes of Health, described the mission of the National Institutes of Health in detail

and the mechanism by which the Institutes awarded research grants. Dr. Sherman advised the subcommittee that the National Institutes of Health planned expenditures in fiscal year 1972 of $792 million for research grants and $232 million for research and development contracts. Significantly, Dr. Sherman and the subcommittee were concerned not about information and records in the possession of the grantees or contractors but about the information submitted by the grantees and contractors to the Institutes, that is, whether that information in the possession of the Institutes should be subject to disclosure under the Act. *U.S. Government Information Policies and Practices, Hearings Before the Subcomm. on Foreign Operations and Government Information of the House Comm. on Government Operations,* 92d Cong., 2d Sess. (Part 9) 3617, 3627, 3629 (1972) [cited in this brief as *1972 House Hearings*].

Congress has not been reluctant to impose obligations and conditions upon the recipients of federal grants. It has by statute imposed requirements that grant recipients keep books and establish accounting systems and that they be subject to audits. *See, e.g.,* 42 U.S.C. § 295h-5 (1976) (grants concerning allied health professions, enacted in 1965); 42 U.S.C. § 2835 (1976) (grants relating to the prevention and treatment of alcohol abuse and alcoholism, enacted in 1970).

It has also subjected grant recipients to federal requirements on matters of social policy not related to handing out and accounting for grant money. For example, in 1964, Congress imposed upon all recipients of federal grants an obligation not to discriminate against any person on the basis of race, color, or national origin in the utilization of federal funds. 42 U.S.C. § 2000d (1976). In addition, one author has listed at least eighteen additional statutes imposing conditions, apart from the requirements of the statutes

creating the grant program, upon the expenditure of federal grant moneys. Madden, *Future Directions for Federal Assistance Programs: Lessons from Block Grants and Revenue Sharing,* 36 Fed. B.J. 107, 115 n.48 (1977). If Congress had wanted to extend the reach of the Act to records of grant recipients, it knew how to do so.

Consequently, the language of the Act, its legislative history, and the authorities that have interpreted and applied it require one conclusion. Because the federal government did not exercise day-to-day control over the activities of the private and state organizations comprising the University Group, the receipt of federal research grants by those organizations does not transform them into federal agencies subject to the Act or their records into agency records. These same considerations also lead to the conclusion that the NIAMDD's right of access to certain records or the FDA reliance upon the University Group's published findings and a limited audit do not transform these organizations into agencies or their records into agency records.

II.

THE FREEDOM OF INFORMATION ACT DOES NOT IMPOSE ANY AFFIRMATIVE OBLIGATION UPON FEDERAL AGENCIES TO OBTAIN DATA FROM PRIVATE OR STATE ENTITIES.

The Freedom of Information Act requires each agency, upon any request for its records, to "make the records promptly available to any person". 5 U.S.C. § 552(a)(3) (1976). By this language, Congress did not intend to enact an information retrieval system. Its goal was simply to require federal agencies and federal employees to provide the documents that they had in their possession to any person who requests those documents. See pages 16-17 and 24-25 above. Neither the language of the Act nor its legislative history suggests that a federal agency must exercise whatever

auditing rights it may have and must obtain documents from private or state entities in response to a request for records. In short, the words "to make . . . available" do not mean "to obtain from outside of the government and make available".

The enforcement provisions of the Act support this conclusion. Section 552(a)(4)(B) states:

> On complaint, the district court of the United States . . . has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant.

"Withhold" means "to hold back", "to keep back or in one's possession". *Webster's New International Dictionary* 2941 (2d ed. 1953). If Congress had intended that federal agencies must acquire documents not in their possession in response to a request, Congress would not have limited the district court's power to (1) enjoining federal agencies from "keeping" agency records in their possession, and (2) ordering the production of records improperly kept in their possession.

The language that Congress chose accurately reflects its goal to make available to the public documents in the possession of federal agencies. None of the instances of agency reluctance to give access to agency records that motivated Congress to pass the Act involved a refusal by an agency to exercise its auditing powers and obtain documents not in its possession. *See generally* H.R. Rep. No. 1497 at 4-5 [1966], U.S. Code Cong. & Ad. News at 2422-23; *1963 Senate Hearings passim; 1965 House Hearings passim; 1972 House Hearings passim; 1973 Senate Hearings passim.*

The Attorney General's interpretation of the Act recognizes this specific intent:

> The requirement of this subsection [5 U.S.C. § 552(3)] imposes no obligation to compile or procure a record in response to a request.

Attorney General's Memorandum at 23-24, *Source Book* at 222-23. Similarly, this Court and other federal courts have given effect to this plain meaning of the Act. In *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 161-62 (1975), this Court stated:

> The Act does not compel agencies to write opinions in cases in which they would not otherwise be required to do so. It only requires disclosure of certain documents which the law requires the agency to prepare or which the agency has decided for its own reasons to create.

See also Nolen v. Rumsfeld, 535 F.2d 890 (5th Cir. 1976), *cert. denied*, 429 U.S. 1104 (1977) (holding that the Act does not require a federal agency to produce missing records and that the United States Army complied with the Act when it made available all of the requested Army records that were extant); *Linker v. Hills*, 453 F. Supp. 556, 561 (S.D.N.Y. 1978) (holding that the Securities Exchange Commission diligently searched missing records and exhibited good faith in assuring that upon locating these records it would make them available and therefore its failure to produce the missing records was not an improper withholding under the Act); *Disabled Officers' Association v. Rumsfeld*, 428 F. Supp. 454, 459 (D.D.C. 1977) (holding that the Act obligates an agency only to produce nonexempt records which it presently has and hence the court should not order the Secretary of Defense to provide in the future the names and addresses of officers who will be retired with a disability).

Since the publication of the *Attorney General's Memorandum*, Congress has amended the Act three times. The two most recent amendments came after this Court's decision in *Sears*. Yet, Congress has not changed the Attorney General's interpretation or the holding of this Court in *Sears*. If Congress wished to change the plain import of the Act and the Attorney

General's and this Court's interpretation, then Congress would have done so.

Congress most likely did not extend the Act to the records of private or state entities that are subject to audit by the federal government because of the drastic impact that such action would have on private and state entities. There are few activities in today's society that are immune from federal auditing powers.[7] In addition, the application of the Freedom of Information Act to private and state organizations subject to federal audit would abrogate many state public information policies as expressed in state statutes and would violate the reasonable expectations of many private persons and organizations that their records are not subject to disclosure to the world at large, but only to one or more particular federal agencies which will only exercise their auditing powers when they need to do so to carry out their functions. If Congress had intended the Act to have so broad a reach, it would at the very least have

[7] The following statutes are merely an example of the federal government's broad powers to require that private and state entities keep records, to demand access to those records, and to acquire the records of private or state entities: I.R.C. § 7602, 26 U.S.C. § 7602 (1976) (any taxpayer or potential taxpayer); 42 U.S.C. §§ 7414, 7616 (1977) (any person who owns an emission source or is subject to the Clean Air Act or any recipient of assistance under that Act); 15 U.S.C. §§ 78q, 78u (1976) (any person subject to the Securities Exchange Act of 1934); 12 U.S.C. § 1906 (1976) (any person subject to the Credit Control Act); 20 U.S.C. § 584 (1976) (state education agency responsible for administering state plans under the National Defense Education Act of 1958); 20 U.S.C. § 1022 (1976) (institutions of higher education and other public and private nonprofit library institutions receiving grants for the acquisition of library resources); 21 U.S.C. §§ 355, 357 (1976) (persons engaged in manufacturing drugs or introducing drugs into interstate commerce); 33 U.S.C. §§ 1318, 1361 (1976) (the owner or operator of any point of discharge and any recipient of financial assistance under the Clean Water Act of 1977); and 29 U.S.C. § 657 (1976) (each employer subject to the Occupational Safety and Health Act of 1970).

considered the interests of these private and state entities before acting.

In the instant case, the NIAMDD has a right to audit certain records of the University Group. 45 C.F.R. § 74.24 (1978). The FDA did a limited audit of the data for 150 patients. 43 Fed. Reg. 52,732, 52,733 (1978). Any documents that the FDA created or obtained in the course of the audit have been turned over to the petitioners (A. 202). The purposes of the Act have been served well.

Because the Act imposes no obligation upon a federal agency to acquire records in response to a request for records and because the Act only applies to records in the possession or day-to-day control of a federal agency, the petitioners' argument fails. Neither the NIAMDD's putative right of access or the FDA's limited audit of some of the data amount to sufficient possession or control of the data to make the data agency records. Similarly, the right of access and a limited audit does not make the University Group's participating schools and hospitals federal agencies.[8] The University Group created the data and it possesses and controls them. The federal government does not. The University Group controls its day-to-day activities. The federal government does not. Here, the data are not subject to the Act.

III.

RELIANCE BY THE FEDERAL GOVERNMENT UPON THE UNIVERSITY GROUP STUDY DOES NOT TRANSFORM THE RAW DATA OF THE STUDY INTO FEDERAL AGENCY RECORDS.

The petitioners argue that the FDA and the Secretary of Health, Education, and Welfare have brought the raw data of the University Group's study under the

[8] There is nothing in the record or in the petitioners unsubstantiated allegations in their brief to suggest that the University Group has served as a data haven to subvert the Act.

Freedom of Information Act because in taking certain regulatory actions they have relied upon the published findings of the study, upon the published report of the committee of the Biometric Society, and upon the limited FDA audit of some of the data. They assert that this alleged reliance is tantamount to reliance upon the raw data and hence that the raw data have been absorbed into the regulatory process.

This argument founders for a number of reasons. In the first place, reliance upon published findings of a study is not reliance upon the unpublished raw data generated by that study. The published findings result from the efforts of the University Group's private and state investigators to analyze the data, to organize them in patterns that the investigators deem appropriate, and to draw conclusions from them. These findings cannot be equated with the raw data any more than a legal brief can be equated with all of the facts and legal authorities that a lawyer may gather in preparing the brief.[9] Similarly, a limited audit of some of the data (*see* 43 Fed. Reg. 52,732, 52,733 (1978)) and reliance upon that data or upon the audit does not "absorb" all of the data into the FDA regulatory process. Accordingly, neither reliance upon published findings nor the FDA's limited audit of some of the data and its reliance upon that audit can reasonably be deemed to create possession of or control over all of the data. In short, neither the FDA nor any other agency of the federal government has ever obtained possession of the raw data or ever exercised day-to-day control over the data or the University Group. Therefore, they are not agency records.

[9] The distinction between published findings and the data underlying those findings was specifically recognized by the Commissioner of Food and Drugs in the administrative proceedings for the withdrawal of approval of new drug applications for phenformin hydrochloride. Proposal to Withdraw Approval of New Drug Applications for Phenformin Hydrochloride (FDA final decision Nov. 15, 1978), *reprinted in* 44 Fed. Reg. 20,967, 20,969 (1979). In his final order withdrawing such approval the Commissioner noted that the record in the withdrawal proceedings contained nearly 400 articles published in the medical literature, none of which were accompanied by the raw data upon which they were based. The Commissioner also observed that the University Group's study was relied upon in those proceedings in the same way as the other articles. Accordingly, the Commissioner did not accept the petitioners' assertions that the administrative law judge erred in admitting the University Group's study into evidence.

Moreover, even if reliance upon published findings and a limited audit were the same as reliance upon the raw data—or, even if the FDA were to inspect every one of the millions of documents in the University Group's possession and were to attempt to rely upon those documents for any regulatory action without acquiring them—the Act would still not apply to the raw data. Such inspection and reliance are not possession of the data and are not sufficient control over the data to make them agency records. FDA's attempt to rely upon the raw data as a basis for regulatory action may not be valid. That, however, is of no concern here.

It follows that the petitioners' reliance argument is in reality an argument that the federal government should have obtained all of the raw data. This of course raises the issue of whether the materials relied upon are substantial evidence upon which regulatory decisions may be based. For example, whether the published findings of the University Group's study and the other material relied upon by the Commissioner of Food and Drugs in proposing the relabeling for all oral hypoglycemic drugs, 40 Fed. Reg. 28,587 (1975), are sufficient to support the proposed relabeling is an issue which must be considered first by the Commissioner and second by any court to which the final decision of the Commissioner may be appealed. It is not an issue before this

Court and it has never been an issue in this case. Indeed, in considering this issue, the court of appeals stated that its holding that the raw data are not agency records raised no implications about the petitioners' ability to obtain the data in the proceedings before the FDA. 587 F.2d at 1134.

The petitioners' argument that reliance makes private and state records federal agency records under the Act, aside from having no basis in the language of the Act, fails for another reason. This argument contradicts one of Congress' main goals in passing theAct: to establish clear and simple guidelines for determining what records are to be made available and to whom. Congress provided that "agency records" should be made available to "any person". These words replaced the elastic and uncertain standards in the original section 3 of the Administrative Procedure Act.[10] That section contained such vague phrases as "matters of official record", "persons properly and directly concerned", and "confidential for good cause", which were difficult to apply and which federal agencies used as grounds for withholding federal documents. *See* S. Rep. No. 813 at 5, *Source Book* at 40; H.R. Rep. No. 1497 at 4-5, [1966] U.S. Code Cong. & Ad. News at 2422-23. The test put forth by the petitioners would inject into the interpretation of the Act an equally elastic and uncertain standard. There is no way to determine how much reliance would be necessary before this metamorphosis of private and state records into federal agency records happened. Moreover, this standard would

[10] This section stated:

> (c) Public Records. — Save as otherwise required by statute, matters of official record shall in accordance with published rule be made available to persons properly and directly concerned except information held confidential for good cause found.

Ch. 324, 60 Stat. 238 (1946), formerly codified in 5 U.S.C. § 1002 (1964).

inextricably entangle the interpretation of the Act with the collateral administrative proceedings in which the federal agency's reliance occurred.[11]

Finally, the reliance test is inappropriate because it attempts to incorporate into the Act consideration of the need for records as a criterion for determining whether those records are "agency records". The petitioners allege a tremendous need for acquiring the raw data. Petitioners' brief at 28, 52. This putative need derives solely from the reliance by the FDA and the Secretary of Health, Education, and Welfare upon the published findings of the University Group study. The petitioners in effect argue that, when the government relies upon the published findings of a study, or a portion of the raw data generated in the study—that is, when the government creates a perceived need in certain persons for all of the data—then all of the data become "agency records" under the Act, even though those data are the records of private and state entities. On the other hand, under the petitioners' argument, if there is no reliance and hence no need, then those private or state records do not become agency records.

[11] The difficulty in applying such a test is illustrated by the administrative proceedings for the suspension and withdrawal of approval of new drug applications for phenformin. On July 25, 1975, the Secretary of Health, Education, and Welfare suspended the approval of new drug applications for phenformin because the drug posed an imminent health hazard. The Secretary based this decision upon reports to the FDA of deaths due to lactic acidosis, data submitted by drug companies and hospitals, reports from other countries, and the published findings of the University Group study. Order of the Secretary Suspending Approval of New Drug Applications for Phenformin, NDA 11-624, 12-752, 17-126, 17-127, (DHEW July 25, 1977).

At the same time, the FDA began the hearings on the permanent withdrawal of approval of the new drug applications. 42 Fed. Reg. 40,959 (1977). After the hearings, the administrative law judge issued an initial decision, in which he ruled that the University Group's study could not be substantial evidence in the proceedings but could form the

It is clear that Congress did not intend this result. The Act eliminated the requirement that the person requesting documents demonstrate a need for those documents. *See* S. Rep. No. 813 at 5, *Source Book* at 40; *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 143 n.10 (1975); *Environmental Protection Agency v. Mink*, 410 U.S. 73, 86 (1973); *Columbia Packing Co. v. United States Department of Argiculture*, 563 F.2d 495, 499 (1st Cir. 1977); *Robles v. Environmental Protection Agency*, 484 F.2d 843, 847 (4th Cir. 1973). The need for documents arising out of regulatory proceedings is similarly irrelevant. The Act was intended to be a disclosure statute, not a discovery statute. *NLRB v. Sears*, 421 U.S. at 143 n.10; e.g.; *Renegotiation Board v. Bannercraft Clothing Co.*, 415 U.S. 1, 24 (1974); *Columbia Packing Co. v. United States Department of Agriculture*, 563 F.2d at 499, 500.

Consequently, whether and to what extent the federal government has relied upon the published findings of the University Group does not alter the plain import of the language of the Act. A person may obtain "agency records". "Agency records" are the records that an agency has created or acquired or that it possesses. Just as federal funding of the study that generated the

basis for expert testimony and for consideration of the safety of phenformin. Proposal to Withdraw Approval of the New Drug Applications for Phenformin Hydrochloride, Docket No. 77N-0150, (FDA initial decision Feb. 8, 1978), *reprinted in* 44 Fed. Reg. 20,977, 20,979 (1979). The Commissioner of Food and Drugs adopted this decision with some modifications. Proposal to Withdraw Approval of New Drug Applications for Phenformin Hydrochloride (FDA final decision Nov. 15, 1978), *reprinted in* 44 Fed. Reg. 20,967 (1979). In doing so, the Commissioner stated that he did not consider the University Group's study in reaching his final decision and that he was not adopting the references to the study in the substantive portions of the initial decision. 44 Fed. Reg. at 20,979. *See also* 44 Fed. Reg. 20,966, 20,966-67 (1979) (denial of petition of reconsideration of final order). Thus, the FDA's reliance upon the published findings of the University Group has varied from some reliance to no reliance.

records or federal access to the records is not equivalent to possession of the records or control over the University Group sufficient to make it a federal agency, federal reliance—by itself or in conjunction with federal funding and federal access—is not possession of the data or control over the University Group. The raw data that petitioners seek are not agency records.

CONCLUSION

For these reasons, the respondent requests that this Court affirm the judgment of the court of appeals and hold that the raw data generated by private and state institutions that conduct a research project funded by federal grants are not agency records within the meaning of the Act and that the Act does not impose an obligation upon federal agencies to acquire these private or state records simply because the federal government may have access to them or may have relied upon published reports based on them.

Respectfully submitted,

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